



510K Summary

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

DATE:	October 17, 2014
APPLICANT:	Genesis BPS, LLC Jerrold B. Grossman President 465 State Route 17 Ramsey, NJ 07446 Tel: 201-708-1400 Email: jgrossman@genesibps.com
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TRADE NAME:	Genesis Rapid Weld STW
CLASSIFICATION NAME:	Transfer set (Blood/Plasma)
COMMON OR USUAL NAME:	Transfer set (Blood/Plasma)
DEVICE CLASSIFICATION AND PRODUCT CODE:	Class II per 21 CFR §864.9875 Hematology Product Code: KSB
PREDICATE DEVICE NAMES:	Fresenius CompoDock, BK040076 Denco Total Containment Device, BK950018

DESCRIPTION OF THE DEVICE:

The Genesis Rapid Weld STW is a medical device used in laboratories, designed for the purpose of making sterile connections in PVC tubing in blood processing applications. The device enables fluid transfer while maintaining a closed system without the need for a consumable (disposable wafer).

INTENDED USE/INDICATIONS FOR USE:

The Genesis Rapid Weld STW is used to make a sterile connection/weld between two segments of PVC tubing used in blood/blood component processing applications.